Written Testimony of
Linda Wallace, Executive Director
Epilepsy Foundation of Connecticut
February 6, 2009
Public Health Committee

Senate Bill #757, An Act Concerning The Filling of Prescriptions for Antiepileptic Drugs

Good morning Senator Harris, Representative Ritter and members of the Public Health Committee. Thank you for giving me the opportunity to testify in support of Senate Bill 757. My name is Linda Wallace and I am Executive Director of the Epilepsy Foundation of Connecticut. I am also the mother of a young adult who has had epilepsy for 23 years.

For the more that 60,000 people in Connecticut with epilepsy, medication is the most common and most cost effective treatment for controlling and/or reducing seizures. This legislation simply requires pharmacists to receive the consent of a patient and their physician before switching from one manufacturer of a particular medication to another manufacturer of the same medication. Physicians and people living with epilepsy may spend many years finding the right dosage and combinations of antiepileptic medications to prevent the occurrence of seizures. A small change in a patient's blood level of antiepileptic medications could easily upset the delicate balance needed to prevent seizures.

It is important to note that the Foundation is NOT and has never been opposed to the use of generic medications. We understand that epilepsy medication can be costly to people with epilepsy and we welcome generic medicines to lower the cost for individuals. We simply want to ensure that a consistent supply of generic medication for people is dispensed and that the physician and patient are notified when it isn't. Epilepsy is a unique condition. Seizures have the potential to be life threatening and can endanger the individual and others around them. This is true particularly if they occur without warning, while the individual is engaged in the various activities of daily life. To risk the occurrence of seizures by switching products without the guidance of the individual's physician is a matter of both public and patient safety.

Until recently there has been limited data on this issue and most evidence was anecdotal or involved a small patient population. Now there are new study results that estimate the risk of an acute event requiring emergency intervention when switching medications at approximately 5%. (See supporting material attached.)

This is not a new issue, nor is it driven by a desire for anyone to benefit except people with epilepsy. For over a decade now, the Epilepsy Foundation has been opposed to switching medications, brand to generic, generic to brand, or from one manufacturer of a generic to another without the consent of the physician and patient. This protection allows for consistency of a person's medication and does not encourage or promote the use of any particular medication – brand or generic. This legislation has the support of the Connecticut State Medical Society, the Connecticut Neurology Association, the American Academy of Neurology, the American Epilepsy Society, the International League Against Epilepsy, the National Black Caucus of Legislators and the National Hispanic Caucus of State Legislators.

Thank you for introducing this legislation, providing us this time to testify and your thoughtful consideration of this important legislation.

EPILEPSY FOUNDATION®
Not another moment lost to seizures™
8301 Professional Place, Landover, MD 20785

August 4, 2008

ROBERT . BONWETSCH
69 SAND PIT RD STE 300
DANBURY, CT 06810

Re: Breakthrough Seizures Associated with AED Switching

Dear Doctor:

The Epilepsy Foundation has long been concerned about the potential risk of breakthrough seizures or toxicity for some epilepsy patients if there is a formulation change in their anti-epileptic drug (AED). The change could be brand to generic, generic to brand, or between the generic versions from different manufacturers. For this reason we believe you as the treating physician and your patient should decide the best treatment option and the Foundation opposes mandatory substitution without physician / patient consent. Our position is consistent with those taken by the American Academy of Neurology, the American Epilepsy Society, the International League Against Epilepsy and almost all international epilepsy organizations.

Until recently there has been limited data on this issue and most evidence was anecdotal or involved a small patient population. As a clinician who treats people with epilepsy, we wanted to make sure you were aware of what we believe are the first case-control analyses of AED switches. Published in *Epilepsia*, Zachry, et al used the Ingenix LabRx Database (i.e., the United Health Group) to evaluate patients with a claim for ambulance, emergency room or inpatient hospital service with a primary epilepsy diagnosis for patients who were previously well controlled (had not utilized these services for epilepsy in the previous six months). Epilepsy patients who received emergent care for epilepsy had 81% greater odds of exposure to switching prior to the breakthrough event when compared to epilepsy patients not receiving emergent care. This result was highly statistically significant ($p=0.0024$).

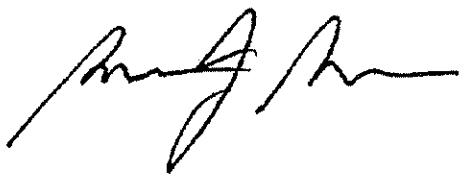
In order to validate the Zachry study, two academic institutions were asked to independently conduct additional case-control studies on other unique nationwide U.S. claims databases. Both studies found almost identical results and are now pending publication. In order to aid clinical application of these studies, each lead author was asked to estimate the attributable risk of an acute event requiring emergent intervention when switching. Based on their study results, each estimated a risk of approximately 5%. It is important to note that these studies only looked at seizures and do not consider toxicity, which anecdotal reports have also linked to formulation changes for some epilepsy patients.

These studies have been shared with the Food and Drug Administration (FDA). Dr. Janet Woodcock, Director Center of Drug Evaluation and Research responded, in part, "We share

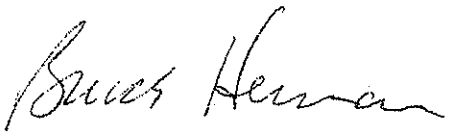
your concern that there could be a limited population of epileptic patients who may be at an increased risk of adverse event with even a minor change in AED formulation, but, we currently do not have adequate data to define such a population, or even to be sure that such a population exists. Before FDA can require any labeling changes or issue a public advisory, an objective prospective study is needed to evaluate PK parameters and adverse events simultaneously with switches in formulations while controlling for all the factors relevant to causation."

The Epilepsy Foundation is collaborating with the American Epilepsy Society (AES) and FDA on a prospective trial as described by Dr. Woodcock and her colleagues. However, completion of such a trial may take at least 1-2 years; in the interim the Epilepsy Foundation believes it is important that clinicians are aware of all relevant data available and the potential risks their patients may face. If you would like to read the full text article, it is available via www.epilepsia.com under the "online early" link.

Sincerely,



Brien J. Smith, MD
Chair, Legal and Government Affairs Committee
Epilepsy Foundation



Bruce P. Hermann, PhD
Chair, Professional Advisory Board
Epilepsy Foundation

cc: Epilepsy Foundation Board of Directors
Epilepsy Foundation Professional Advisory Board
Epilepsy Foundation Affiliates